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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0313]

Lisett Raventos: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Lisett Raventos from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Lisett Raventos was convicted of a felony under Federal law for conduct that relates to the development or approval, including the process of development or approval, of a drug product under the FD&C Act. Ms. Raventos was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of December 29, 2021 (30 days after receipt of the notice), Ms. Raventos had not responded. Ms. Raventos's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On March 5, 2021, Ms. Raventos was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against her in the U.S. District Court for the Southern District of Florida, after her plea of guilty to one count of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 1349.

The factual basis for this conviction is as follows: Ms. Raventos was a clinical study coordinator at Unlimited Medical Research, LLC. From about September 2013 through June 2016, Ms. Raventos conspired with others to unlawfully enrich herself by making materially false representations about clinical trials; fabricating data and the participation of subjects in those clinical trials; concealing from FDA, sponsors, and contract research organizations the fact that the data and participation of subjects had been fabricated; and inducing sponsors and contract research organizations to pay money for Ms. Raventos and her co-conspirators' own benefit. Specifically, one of Ms. Raventos's co-conspirators entered into a contract with a Contract Research Organization (CRO), retained by a drug manufacturer (Sponsor) to hire clinical investigators and to manage clinical trials. Ms. Raventos's co-conspirator entered into a contract with the CRO to conduct a clinical trial at Unlimited Medical Research site in return for payment. The clinical trial was for an investigational drug intended to treat pediatric asthma in children between the ages of 4 and 11 years.

Ms. Raventos represented herself to be the Site Director, Director of Clinical Operations, and the Study Coordinator for this clinical trial. In those roles, Ms. Raventos was responsible for complying with the study protocol, including administering the study drug to subjects in the

study and preparing written records, known as case histories, which documented the participation of subjects in the clinical trial. Ms. Raventos participated in a scheme to defraud the Sponsor by fabricating the data and participation of subjects in the clinical trial in a variety of ways: Ms. Raventos and her co-conspirators falsified medical records to portray persons as legitimate study subjects when they were not. In addition, Ms. Raventos and her co-conspirators made it appear as though pediatric subjects made scheduled visits to Unlimited Medical Research when they had not, made it appear as though subjects had taken the study's drugs as required when they had not, and made it appear that the study subjects had received checks as payment when they had not.

As a result of this conviction, FDA sent Ms. Raventos by certified mail on November 19, 2021, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Ms. Raventos was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Ms. Raventos an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Raventos received the proposal on November 29, 2021. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Raventos has been convicted of a felony under Federal law for

conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Raventos is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see DATES) (see section 306(a)(2)(A) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Raventos, in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Raventos provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Ms. Raventos during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a "drug product" is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd)).

Any application by Ms. Raventos for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2021-N-0313 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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